

REMARKS

Status of the Claims

Claims 3-7, 9, 10, 17, 20, 22, 45, 50-52, 54-60, 82-83, 85-90, 96, 98, 114, 115, 117, 118, 120, 121, 123-126, 128-130, and 132-142 are pending. Claims 11, 13, 61, 63-80, 95, 116, 119, 122, 127, and 131 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Applicants expressly reserve the right to file continuing applications directed to the deleted subject matter. New claims 133-142 have been added. Claims 117, 120, and 123 have been amended to place them in independent claim format. Claims 125 and 129 have been amended to correct typographical errors. Support for the claim amendments and the new claims may be found in the originally-filed specification and claims. No new matter has been added by way of amendment. Reconsideration and withdrawal of the rejection are respectfully requested.

Information Disclosure Statement

Applicants note that the Gao *et al.* reference listed on the Form PTO-1449 submitted on February 2, 2005 was not considered. The non-patent literature document is attached herewith, along with the appropriate statement and fee and a new Form PTO-1449. Applicants request that the Examiner consider the reference and return a fully-initialed copy of the Form PTO-1449 with the next communication.

The Rejections under 35 USC §112 Should be Withdrawn

Claims 61, 127, and 131 have been rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for vaccine compositions. While Applicants respectfully disagree with the rejection, claims 61, 127, and 131 have been cancelled to expedite prosecution, thereby obviating the rejection.

The Rejection under 35 USC §102(b) or 35 USC § 103(a) Should be Withdrawn

Claims 3-7, 9-11, 13, 17, 20, 22, 45, 50-52, 54-61, 82-83, 85-88, 90, 95-96, 98, 114, 115, and 116-132 have been rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over PCT Publication No. (Berthet *et al.*). Claims 11, 13, 61, 95, 116, 119, 122, 127, and 131 have been cancelled

to expedite prosecution, rendering the rejection of these claims moot. The rejection is respectfully traversed as applied to the remaining claims.

Claims 117, 120, and 123 of the present application (from which all the other claims depend) are directed to immunogenic compositions comprising at least 3 different antigens selected from at least 3 different categories of Neisserial antigens. Claim 117 recites a composition including at least one Neisserial autotransporter antigen, at least one Neisserial adhesin antigen, and at least one different antigen, where the different antigen is selected from Neisserial toxin antigens, Neisserial Fe acquisition protein antigens, and Neisserial membrane associated proteins. Claim 120 recites a composition including at least one Neisserial autotransporter antigen, at least one Neisserial Fe acquisition protein antigen, and at least one different antigen, where the different antigen is selected from Neisserial toxin antigens, Neisserial adhesin antigens, and Neisserial membrane associated proteins. Claim 123 recites a composition including at least one Neisserial autotransporter antigen, at least one Neisserial membrane associated antigen, and at least one different antigen, where the different antigen is selected from Neisserial toxin antigens, Neisserial adhesin antigens, and Neisserial Fe acquisition protein associated antigens.

The Examiner points to claim 15 of the Berthet *et al.* reference as anticipatory of the claims of the present application. This claim teaches a bleb preparation having one or more upregulated genes selected from a list of 21 antigens. However, the Berthet *et al.* reference does not teach that the preparation should have at least 3 different antigens, where each antigen is selected from one of 3 different antigen classes as recited in claims 117, 120, and 123. Rather, the Berthet reference teaches a large genus of possible antigen combinations. In fact, claim 15 of this publication encompasses 7980 possible combinations containing three different antigens.

According to the relevant case law, lists and genera should be treated differently when determining whether a reference is anticipatory. For example, in *Atofina v. Great Lakes Chem Corp.*, the Federal Circuit stated, “[i]t is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus.” *Atofina v. Great Lakes Chem Corp.* 441 F.3d 991, 992 (Fed. Cir. 2006). Accordingly, because the Berthet *et al.* reference teaches a large genus of possible antigen combinations but does not list the specific combinations of 3 different antigens selected from 3 specified antigen classes as recited in claims 117, 120, and

123, this reference does anticipate the subject matter of these claims or their respective dependent claims.

Furthermore, claims 3-7, 9, 10, 17, 20, 22, 45, 50-52, 54-60, 82-83, 85-90, 96, 98, 114, 115, 117, 118, 120, 121, 123-126, 128-130, and 132-142 are not obvious in view of the Berthet *et al.* reference because this reference provides no suggestion or rationale to combine three different antigens from the three classes recited in claims 117, 120, and 123 to form an immunogenic composition. It is the present application, rather than the Berthet *et al.* reference, that demonstrates the advantage of immunogenic compositions comprising 3 different antigens from the specified antigen classes. See, for example, Example 20.

In view of the above amendments and arguments, all grounds for rejection under 35 USC §102 or 35 USC §103(a) have been obviated or overcome. Reconsideration and withdrawal of the rejections are therefore respectfully requested.

The Double Patenting Rejections Should be Withdrawn

Claims 3-7, 9-11, 13, 17, 20, 22, 45, 50-52, 54-61, 82-83, 85-88, 90, 95-96, 98, 114-115, and 116-132 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-57 and 60-71 of copending Application No. 10/523,114 and over claims 1-8, 14-20, 53, and 59-60 of copending Application No. 10/523,044. Claims 11, 13, 61, 95, 116, 119, 122, 127, and 131 have been cancelled to expedite prosecution, rendering the rejection of these claims moot. Applicants will address the rejections with respect to the remaining claims at such time as the claims of Application Nos. 10/523,114 and/or 10/523,044 are deemed allowable and the rejection of the present application becomes non-provisional.

CONCLUSION

It is believed that the current application is now in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, an interview would expedite prosecution, the Examiner is invited to call the undersigned, who may be reached at (919) 483-1467.

Respectfully submitted,

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